

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: David White

Application No.:

Group No.: N/A

Filed: Herewith

Examiner: N/A

For: COMPOSITIONS, KITS AND METHODS FOR PROGNOSTICATION,  
DIAGNOSIS, PREVENTION, AND TREATMENT OF BONE-RELATED  
DISORDERS AND OTHER DISORDERS

Mail Stop Patent Application  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

**List of Sections Forming Part of This Information Disclosure Statement**

The following sections are being submitted for this Information Disclosure Statement:

1.  Preliminary Statements
2.  Forms PTO/SB/08A and 08B (substitute for Form PTO-1449) (3 pages)
3.  Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted

---

**CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10\***

I hereby certify that, on the date shown below, this correspondence is being:

**MAILING**

deposited with the United States Postal Service in an envelope addressed to Mail Stop Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

**37 C.F.R. SECTION 1.8(a)**

**37 C.F.R. SECTION 1.10\***

with sufficient postage as first class mail.

as "Express Mail Post Office to Addressee"  
Mailing Label No. EL992152675US

**TRANSMISSION**

transmitted by facsimile to the Patent and Trademark Office.

  
Signature

Date: September 18, 2003

Sean Hunziker  
(type or print name of person certifying)

**Preliminary Statements**

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. section 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

**Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted**

This application relies, under 35 U.S.C. section 120, on the earlier filing date of prior application Serial No.: 09/ 628,495, filed on July 28, 2000.

The following references were submitted to, and/or cited by, the Office in the prior application(s) and, therefore, are not required to be provided in this application. However, in the event additional copies are necessary, the undersigned will submit such copies upon request.

September 18, 2003

MILLENNIUM PHARMACEUTICALS, INC.

By   
Kerri Pollard Schray  
Registration No. 47,066  
75 Sidney Street  
Cambridge, MA 02139  
Telephone – (617) 551-3676  
Facsimile – (617) 551-8820

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO				C mplete if Known	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>				<b>Application Number</b> <b>Filing Date</b> Herewith <b>First Named Inventor</b> David White <b>Group Art Unit</b> N/A <b>Examiner Name</b> N/A <b>Attorney Docket Number</b> MPI99-130P1RCN1M	
Sheet	1	of	1		

## U.S. PATENT DOCUMENTS

## FOREIGN PATENT DOCUMENTS

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Unique citation design number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>8</sup>Applicant is to place a check mark here if English language Translation is attached.

**Burden Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, D.C. 20231.

DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, D.C. 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>				Application Number	
Sheet	1	of	1	Filing Date	Herewith
				First Named Inventor	David White
				Group Art Unit	N/A
				Examiner Name	N/A
				Attorney Docket Number	MPI99-130P1RCN1M

<b>OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS</b>				
Examiner Initials*	Cite No. <sup>1</sup>	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and-or country where published.		T <sup>2</sup>
	C1	Alberts et al., <i>Molecular Biology of the Cell</i> , Garland Publishing, Inc. 1 <sup>st</sup> Ed.:127-141 (1983)		
	C2	Blechschmidt et al., GenBank Accession No. AF003625, January 1, 1998		
	C3	Cardinali et al., <i>J. Pineal Res.</i> 34:81-87 (2003)		
	C4	Conway, S. et al., <i>Journal of Biological Chemistry</i> 275(27):20602-20609 (2000)		
	C5	DeRienzo et al., <i>Perspective in Comparative Endocrinology</i> :1075-1079 (2001)		
	C6	Drew et al., <i>J. Neuroendocrinol.</i> 10:651-661 (1998)		
	C7	Gubitz et al., GenBank Accession No. AAC21462, March 2, 1999		
	C8	Gubitz et al., <i>Genomics</i> 55:248-251 (1999)		
	C9	Gubitz et al., <i>Genomics</i> 55(2):248-251 (1999)		
	C10	Lewin Genes II, <i>John Wiley &amp; Sons, Inc.</i> :221-236 (1985)		
	C11	McDougall et al., <i>Endocrinology</i> 144(5):1994-1999 (2003)		
	C12	Murray et al., <i>Harper's Biochemistry</i> , Appleton & Lange 21 <sup>st</sup> Ed. Chapters 10, 11 and 41 (1990)		
	C13	Peterlik, M. et al., <i>Experimental Gerontology</i> 32(4-5):577-586 (1997)		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Unique citation design number. <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, D.C. 20231.

DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, D.C. 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO				Complete if Known													
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>				<table border="1"> <tr> <td>Application Number</td> <td></td> </tr> <tr> <td>Filing Date</td> <td>Herewith</td> </tr> <tr> <td>First Name of Inventor</td> <td>David White</td> </tr> <tr> <td>Group Art Unit</td> <td>N/A</td> </tr> <tr> <td>Examiner Name</td> <td>N/A</td> </tr> <tr> <td>Attorney Docket Number</td> <td>MPI99-130P1RCN1M</td> </tr> </table>		Application Number		Filing Date	Herewith	First Name of Inventor	David White	Group Art Unit	N/A	Examiner Name	N/A	Attorney Docket Number	MPI99-130P1RCN1M
Application Number																	
Filing Date	Herewith																
First Name of Inventor	David White																
Group Art Unit	N/A																
Examiner Name	N/A																
Attorney Docket Number	MPI99-130P1RCN1M																
Sheet	2	of	2														

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include the name of the author (in CAPTIAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and-or country where published.	
	C14	Reppert et al., GenBank Accession No. U52218, July 28, 1996	
	C15	Reppert et al., GenBank Accession No. U52219, July 28, 1996	
	C16	Reppert et al., <i>FEBS Lett.</i> 386:219-224 (1996)	
	C17	Reppert, S. M., et al., <i>FEBS Lett.</i> 386(2-3):219-224 (1996)	
	C18	Rodan, <i>Bone</i> 13:S3-S6 (1992)	
	C19	Roth et al., <i>J. Biol. Chem.</i> 31:22041-22047 (1999)	
	C20	<i>Stedman's Medical Dictionary</i> , Physicians' Desk Reference, Medical Economics Company Inc. (2002)	
	C21	Stein, W. D., <i>Channels, Carriers, and Pumps : An Introduction to Membrane Transport</i> , Academic Press 1st Ed. Chapter 3:Ion Channels Across Cell Membranes:73-125 (1990)	
	C22	Weaver and Reppert, <i>NeuroReport</i> 9:109-112 (1996)	
	C23	Wiren et al., <i>J. Endocrinol.</i> 175(3):683-694 (2002)	
Examiner Signature		Date Considered	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Unique citation design number. <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, D.C. 20231.

DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, D.C. 20231.